



**CIRCULATORY SYSTEM DEVICES PANEL
AGENDA*****June 12, 2014*****Circulatory System Devices Panel
LUTONIX® 035 Drug Coated Balloon PTA Catheter
Holiday Inn Germantown, MD**

On June 12, 2014, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the LUTONIX 035 Drug Coated Balloon PTA Catheter sponsored by Lutonix, Inc. The LUTONIX 035 Drug Coated Balloon PTA Catheter (LUTONIX DCB) is an over-the-wire percutaneous transluminal angioplasty (PTA) catheter with a paclitaxel-based drug coating on the surface of the balloon. The LUTONIX DCB is compatible with a 0.035" guidewire and has balloon sizes ranging from 4 millimeters (mm) to 6 mm in diameter and 40 mm to 100 mm in length. The LUTONIX DCB catheter is available in 75 centimeters (cm), 100 cm and 130 cm working lengths.

8:00 a.m.	Call to Order Introduction of Committee	Richard Page, MD Chairperson
	Conflict of Interest Statement	Jamie Mae Waterhouse, MBA Designated Federal Officer
8:15 a.m.	Sponsor Presentation	
9:45 a.m.	Sponsor Q&A	
10:00 a.m.	Break	
10:15 a.m.	FDA Presentation	
11:45 a.m.	FDA Q&A	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Panel Deliberations	
3:15 p.m.	Break	
3:30 p.m.	FDA Questions to the Panel	
5:00 p.m.	FDA and Sponsor Summations	
5:30 p.m.	Panel Vote	
6:00 p.m.	Adjournment	

* **Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.